



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner Lyle A. Alexander
ART UNIT 1743

In re application of
E. Alan Bates et al.
Application No. 08/935,629
Filed 09/23/97
For ASSAYING DEVICE

#25
PP
D 2001

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
Washington, DC 20231

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I, Gary Hoffman, declare as follows:

1. I am the third joint inventor for this application.
2. Versions of the invention as shown in Figs. 1-3 have been marketed since July-August 1997.
3. The invention has developed a loyal following, as indicated by the growth in quantity sold, as follows: 109,096 tests in 1997, 228,216 tests in 1998, 456,855 in 1999 and 561,750 in 2000.
4. This growth has been on the basis of the technological merits of the invention. I base this conclusion particularly on knowledge gained from an incident in the history of the product, when we temporarily had to stop supplying the product in late 1998 and early 1999, because of a problem with quality control involving test strips that produced ambiguous results or false positives.
5. When the supply was stopped temporarily for a few weeks, we offered regular customers an alternative product without a cap to meet their immediate needs.
6. Customers actually complained about having to use such alternatives and pressed us to get the supply with caps started

again as soon as possible.

7. Complaints about lack of caps came particularly from drug treatment centers because they photocopied the results for their permanent records.

8. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; such statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and may jeopardize the validity of the application or any patent issued thereon.

Signature: Gary Date: 10-8-01